HFI-135

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341
Fax: 504-589-6360

November 10, 1998

WARNING LETTER NO. 99-NOL-06

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Scelfo, Jr. Owner/President
Bubba's Crab Factory, Inc.
1809 Canal Drive
Franklin, Louisiana 70538

Dear Mr. Scelfo:

During an inspection of Bubba's Crab Factory, Inc., located at 1809 Canal Drive, Franklin, Louisiana, conducted on September 24, 25 and 29, 1998, our investigator documented numerous insanitary conditions in your picked crabmeat operation. This causes your finished product, picked crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

Objectionable insanitary conditions noted included:

1. Cooked crabs in each of three cooking baskets contacted insanitary objects, including the metal chain, electrical cord and hook of the basket hoist mechanism;

2. Two perforated crates containing cooked crab claws were placed on the wet backing room floor. The cooked claws in these crates were subsequently commingled with other cooked claws. Also, one of the two crates that had been on the wet floor was stacked on other perforated crates containing cooked crab products;

3. An employee walked on the stainless steel platform in the in-process cooked crab refrigerated cooler after walking on the wet cooking/backing room floor and in areas outside of the processing plant. The employee then placed seven perforated crates of cooked product on the previously walked on area of the platform without first washing and sanitizing the area;

4. Cooked crabs directly contacted the pitted backing table which was not adequately cleaned or sanitized prior to backing operations. Encrusted residues from previous operations coated the rough seam welds of the backing table;

5. The cooked crab weigh scale platform and the backing table stand were not washed and sanitized prior to operations, during which perforated crates of cooked crabs and claws were placed on both;

6. Employee hand sanitizing dip bowls were not documented as monitored on your firm's sanitation and temperature monitoring records;

7. A picking employee with more than three inches of hair exposed from a cap, ran a picking knife through the side of his hair behind his ear then resumed picking crabmeat without washing or sanitizing the knife;

8. Seven of twelve employee hand sanitizing dip bowls had no detectable or low amounts of iodine present; and,

9. A thermometer probe that contacted cooked crab products was not sanitized prior to the contact.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the above noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Additionally, this inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123).

The seafood processing regulations, which became effective on December 18, 1997, require you to implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operations to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, of your crab picking plant, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA-3501) and the FDA-483 which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

- Failure to identify any post cooking steps (such as overnight storage of cooked crabs, backing, picking, packing and refrigerated storage of finished product) as critical control points (CCP) of the significant hazard pathogen growth/toxin formation as required under 21 CFR Part 123.6(c)(2). The critical control point begins when a cooked ready-to-eat product is further handled or contacts surfaces that were not heated along with the product. At this point, time above a critical temperature becomes a critical limit and must be monitored, unless it is a very short time, e.g. 30 minutes;

- Failure to adequately monitor the hazard of pathogen growth/toxin formation due to time/temperature abuse during post refrigerated chilling steps, such as processing/picking and packing as required by 21 CFR Part 123.6(c)(4);

- Failure to monitor or document sanitation activities before or during the cooking and backing operations as required by 21 CFR Part 123.11(b);

- Failure to document the monitoring of the prevention of cross contamination, the protection of food and food packaging materials from adulterants and the labeling, storage and use of toxic compounds as required by 21 CFR Part 123.11(b);

- Failure to adequately document the HACCP Steaming Records in that the records are not completed by the individual performing the activity, they are not completed concurrently with the activity, nor is the actual steam cooking time recorded as required by 21 CFR Part 123.6(b);

- Failure to record the actual internal refrigerated cooler temperature on the Chilling Monitoring Record, as required by 21 CFR Part 123.6(b);

- Failure to record the actual internal temperature of the cooked crab product on the Chilling Monitoring Record as required by 21 CFR Part 123.6(b);

- Failure to complete records that monitor various cooler or product temperatures for pathogen growth/toxin formation hazards as required by 21 CFR Part 123.6(b). Specifically, Steaming Record documents for June 1, 1998 and May 31, 1998, do not document that batches of crabs cooked those days were placed into refrigerated storage. Also, there is no documentation that product processed by meat extraction on May 5 and 12, and June 1, 1998, was packed and stored as finished product. Additionally, for September 10, 1998, there is no documentation of crab temperature, internal cooler temperature, or employee initials for three batches of cooked crabs that were placed in refrigerated storage. Further, for August 11 and 31, 1998, the packing room temperature was not recorded for the processed crabmeat;

- Failure to adequately monitor and provide corrective actions for insanitary employee activities which occurred during packing and picking operations as required by 21 CFR Part 123.11(c). For example: a) three employees wore caps that exposed approximately two inches of hair; b) four employees used etched/ornate knives to pick crabmeat and crack crab claws; and, c) a packing room employee handled paper and then, without washing and sanitizing her hands, contacted picked crabmeat in the plastic tubs as she collected crabmeat from pickers;

- Failure to record the monitoring of chlorine sanitizer levels on the Sanitation Report or Processing Records as required by 21CFR Part 123.11(b); and,

- Failure to record the time of monitoring activities on the Sanitation Report, and to document the date of review of the HACCP monitoring records and the Sanitation Report as required by 21 CFR Part 123.11(b).

Objectionable equipment and insanitary conditions as listed on Form FDA-483 and Form FDA-3501 are an indication that sanitation monitoring [21 CFR 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions are listed in paragraph two (2) of this letter.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on these HACCP matters within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply, relating to these insanitary and HACCP concerns, should be directed to the Food and Drug Administration, Attention: Nicole F. Hardin, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896.

If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Ms. Hardin at (504) 589-7166 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

Charles H. Scarborough /for

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483